



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: AAV-Mediated Aquaporin Gene Transfer to Treat Sjögren's Syndrome

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive license to MeiraGTx, having a principal place of business in New York, New York, U.S.A. to practice the inventions embodied in the following patent applications, entitled "AAV-mediated aquaporin gene transfer to treat Sjögren's syndrome":

1. U.S. Provisional Patent Application No. 61/695,753 filed August 31, 2012 (HHS Ref. No. E-139-2011/1-US-01);
2. PCT Application No. PCT/US2013/057632, filed August 30, 2013 (HHS Ref. No. E-139-2011/1-PCT-02);
3. Australia Patent Application No. 2013308470, filed February 25, 2015 (HHS Ref. No. E-139-2011/1-AU-03);

4. Canada Patent Application No. 2882763, filed February 20, 2015 (HHS Ref. No. E-139-2011/1-CA-04);
5. European Patent Application No. 13773443.0, filed March 30, 2015 (HHS Ref. No. E-139-2011/1-EP-05);
6. US Patent Application No. 14/423,774, filed February 25, 2015 (HHS Ref. No. E-139-2011/1-US-06).

The patent rights in these inventions have been assigned to the Government of the United States of America. The territory of the prospective license may be worldwide, and the field of use may be limited to adeno-associated virus (AAV) vector mediated gene delivery of human aquaporin-1 (hAQP1) in Sjögren's syndrome patients with associated xerostomia and /or xerophthalmia.

DATE: Only written comments and/or applications for a license that are received by the National Institute of Dental and Craniofacial Research, Office of Technology Transfer and Innovation Access on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

FOR FURTHER INFORMATION CONTACT: Requests for a copy of the patent application(s), inquiries, comments and other materials relating to the contemplated license should be directed to: Sally Hu, Ph.D., M.B.A., Senior Licensing and Patenting Manager, Office of Technology Transfer and Innovation Access, National Institute of Dental and Craniofacial Research, National Institutes of Health, BLDG 1 DEM, RM667, 6701 Democracy Blvd, Bethesda, MD 20817; Telephone: (301) 594-2616; Facsimile:

(301) 496-1005; E-mail: sally.hu@nih.gov. A signed confidential disclosure agreement may be required to receive copies of the patent application assuming it has not already been published under the publication rules of either the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: This subject technology is directed to the methods of using AAV vectors to deliver the hAQP gene into a salivary gland or a lachrymal gland in patients who suffer from Sjögren's syndrome. Sjögren's syndrome is a systemic autoimmune disease in which immune cells attack and destroy the glands that produce saliva and tears, resulting in progressive dry mouth and dry eyes. In a mouse model of Sjögren's syndrome, administration of hAQP-1 to salivary glands can restore salivary secretion and reduce inflammation in the glands.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404. The prospective exclusive license may be granted unless, within fifteen (15) days from the date of this published notice, the Office of Technology Transfer and Innovation Access, National Institute of Dental and Craniofacial Research receives written evidence and argument that establishes that the grant of the contemplated license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.

Properly filed competing applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made

available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: April 22, 2016

David W. Bradley,

Director

Office of Technology Transfer and Innovation Access

National Institute of Dental and Craniofacial Research

National Institutes of Health

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